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# NONPRESCRIPTION MEDICATIONS AND SELF-CARE

## Nonprescription Drug Therapy: Issues and Opportunities

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Nonprescription drug therapy is tightly woven into the fabric of American health care. Market forces are expected to contribute to significant expansion of nonprescription drug use. Consumers place high value on nonprescription drug therapy; however, self-medicating patients frequently need assistance from a learned intermediary to assure optimal integration of nonprescription drug therapy into the total care regimen. Pharmacist-assisted self-care holds vast potential to serve the public interest, but this expanded practice role will require higher levels of professional practice commitment by American pharmacy. That commitment must be supported by practice-relevant, competency-based, patient-centered college and school of pharmacy curricula and continuing education that assures perpetual intellectual proficiency in nonprescription drug pharmacotherapy. That knowledge and competency must be integrated holistically into the total mix of patient comorbidity and polypharmacy. The pharmacist-assisted self-care business and professional practice model must be further facilitated by state and national pharmacy organizations, chain and independent community pharmacy, pharmacy wholesalers, and others. Consumers await expanded and differentiated pharmacy-based, pharmacist-provided medication therapy management services focused on the safe, appropriate, and effective selection, use, and monitoring of nonprescription drugs therapy.

**Keywords:** self-care, nonprescription medication, curriculum

## INTRODUCTION

Billions of health problems are treated annually with one or more nonprescription drugs as primary therapy or major adjunctive therapy. The prevalence of nonprescription drug use, as well as the potential for therapeutic misadventures, begs for attention by the profession of pharmacy.

Wise consumers are seeking a higher degree of ownership in their own health care as well as a more collaborative partnership with health care providers, particularly their physician and pharmacist. In the nonprescription drug and nutritional supplement domains, consumers too often engage in independent self-care. Nonprescription drugs are powerful pharmacologic agents, many formerly prescription-only, and must be selected, used, and monitored with the same degree of care as prescription drugs.

Pharmacists are increasingly committed to assuring safe, appropriate, and effective use of nonprescription medication and nutritional supplements as a core professional responsibility. Pharmacists are strategically positioned to serve as gatekeepers (portal-of-entry) into the health care system for self-medicating patients. Primary care and disease management opportunities for pharmacists with self-medicating consumers are vast.

Consumers need objective, informed information on nonprescription drugs and nutritional supplements. Package labeling of nonprescription drugs, though improved in content and readability, can never adequately address the seemingly infinite therapeutic issues associated with comorbidity and polypharmacy involving prescription drugs, nonprescription drugs, and/or nutritional supplements. In the nonprescription drug and nutritional supplement domains, the model of collaboration exhibited in Figure 1 is strongly encouraged. This collaboration discourages self-care and calls for a new model of health care classified as *pharmacist-assisted self-care*.

Pharmacist-assisted self-care defines the pharmacist as a professional entity grounded in service provision and differentiates the pharmacy from thousands of other retail outlets that sell only nonprescription medications. Pharmacist-assisted self-care creates substantial business and professional opportunities for pharmacists, while providing higher levels of health-care value for consumers. Converging clinical and economic factors supportive of the pharmacist-assisted self-care model are presented in the following section.

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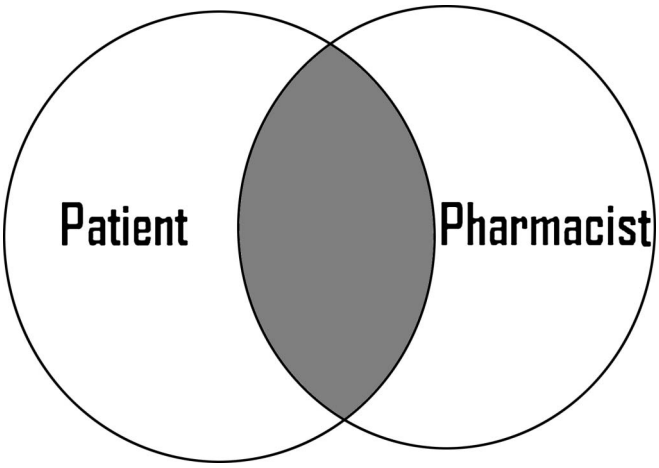


Figure 1. Pharmacist-assisted self-care model.

## CONVERGING CLINICAL AND ECONOMIC FACTORS

### Consumer Self-Care Megatrends

Consumer behaviors, beliefs, and attitudes provide context to the opportunities and challenges surrounding the selection, use, and monitoring of nonprescription drugs. Consumers have confidence in nonprescription drugs. A survey by the National Council for Patient Information and Education revealed that 92% of consumers considered nonprescription drugs effective and 83% of consumers considered them safe. In the same survey, 73% of consumers reported they preferred to treat symptoms themselves with nonprescription drugs. Of adults, 38% reported a higher degree of nonprescription drug use now than 2 years ago.[1,2]

Unfortunately, only 37% of patients consuming nonprescription drugs seek assistance from any health professional regarding proper selection or use. In a National Consumer League survey, only 16% of consumers reported reading the nonprescription drug label completely and 10% of surveyed consumers indicated that they did not read the label at all before taking nonprescription drugs. Further, 44% of 4,300 adults exceeded the recommended dose of nonprescription pain relievers.

Consumer acceptance of nonprescription drugs is high, but when consumers self-medicate without first consulting their pharmacist, issues of safety and inappropriate and/or ineffective use arise for a significant percentage of the population.

### Consumer Value

As health care costs escalate, consumers are seeking more value for their health care dollar. The value equation (value = quality/cost) is addressed well with appropriate nonprescription drug therapy. Approximately 43 million Americans are uninsured, millions more are underinsured, and the insured are being faced with higher deductibles, copayments, and coinsurance. Nonprescription drugs, many of which are former prescription drugs, represent low cost alternatives to many prescription medications. The quality component of the value equation is addressed primarily by the United States Food and Drug Administration (FDA). Nonprescription drugs are held to the same strict FDA standards for safety, effectiveness, purity, stability, and overall quality as prescription drugs. Labeling standards are high and consistent.

### Treatable Conditions

Safe and effective nonprescription drugs are used to manage or assist in the management of more than 450 medical conditions, many of which occur tens of millions of times per year. For example, nonprescription drugs are primary in the treatment of non-migraine headaches and heartburn. Nonprescription drugs in 2 therapeutic categories ($H_2$-receptor antagonists and proton pump inhibitors) are now available in prescription-drug strengths to treat heartburn. Medical conditions such as the common cold, allergic rhinitis (seasonal and perennial), dysmenorrhea, fever, constipation, diarrhea, contact dermatitis, and many other medical conditions are treatable with nonprescription drugs as primary therapy. Nonprescription drugs, selected and utilized properly, can be highly effective in ameliorating symptoms while avoiding trivial or unnecessary physician office visits and more expensive, but not always more effective, prescription drug use.

### The Aging of America

Currently, elderly patients represent 13% of the US population, yet consume far more than 13% of nonprescription drugs. This disproportionate utilization reflects age-related morbidity and comorbidity. Utilization of nonprescription drugs in the elderly population is expected to increase as the 76 million Americans born between 1946 and 1964 (ie, the "baby boomer bubble") are now 42 to 60 years of age.

### Prescription to Nonprescription Drug Switches

A significant market trend is for the FDA to switch prescription drugs with a positive safety profile to nonprescription status. Selected drugs that have moved from prescription only status to nonprescription status include Advil, Afrin, Drixoral, Aleve, Pepcid AC, Zantac, Nicorette, Rogaine, Lamisil (topical), Claritin, Claritin D, and Prilosec OTC. More than 1,000 nonprescription products contain ingredients that were formerly only available by prescription. Nonprescription products that were

formerly available only with a prescription comprise more than 30% of the nonprescription drug market.

Historically, the prescription-to-nonprescription drug switches have been at a fraction (usually half) of the most commonly utilized prescription strength. However, the last 4 FDA changes in drug status have been for the most widely employed prescription strength (eg, loratidine [Claritin], 10 mg; ranitidine [Zantac 150], 150 mg; famotidine [Pepcid AC Maximum Strength], 20 mg; and omeprazole [Prilosec OTC], 20 mg). Social and economic forces are expected to foster additional prescription-to-nonprescription switches. Additionally, commercial insurers, pharmacy benefit management companies, governmental entities, and employers are increasingly expressing the desire and intent to provide nonprescription drugs as a covered benefit.

**Improved Labeling**

The labeling of nonprescription drugs has improved tremendously over the past few years. The new ''Drug Facts'' label format is patterned after the ''Nutrition Facts'' label on food products. Print is larger and bolder, and information is organized consistently in sections. The information is structured so that directions for use are more likely to be understood and followed by the typical consumer.

However, the label on nonprescription drug packaging cannot and does not address all relevant issues surrounding comorbidities and polypharmacy. The inadequacy of labeling is confounded by the functional illiteracy rate in the United States being approximately 20%.[3] Further, approximately 35% of the US adult population reads and comprehends at the $6^{th}$- to $10^{th}$-grade level. Much of the remainder of the US population is intellectually and/or attitudinally unprepared to make objective and informed diagnostic and therapeutic decisions for themselves or those in their care. These realities support the logic for the pharmacist-assisted self-care model (Figure 1) for fostering the safe, appropriate, and effective use of nonprescription drugs.

**Complexity of Care**

The complexity of care, comorbidity, and polypharmacy call for integrated thought, application of therapeutic logic, and clinical judgment that goes far beyond package labeling. All prescription or nonprescription drugs are powerful chemical entities with well-defined pharmacology and toxicology. When one considers the heath status of individual patients; the contraindications, warnings, precautions, adverse effects, drug-drug interactions, and administration of and dosage considerations for each drug; the special considerations in special populations (eg, pregnancy, lactation, smoking, age, renal status, hepatic function) and how a coexisting disease or add-on nutritional supplement might influence therapeutic outcomes, then drug therapy management and oversight by an informed health professional become critical. That individual is logically the pharmacist.

**Learned Intermediary**

The pharmacist is the only health professional who receives in-depth formal education and skill development in nonprescription drug therapy. Further, the pharmacist is readily available in the community to assist patients in diagnosing self-treatable conditions and guiding nonprescription drug selection, use, and monitoring in the total patient care context that may involve other nonprescription drugs, prescription drug use, and/or consumption of one or more nutritional supplements.

Access to the pharmacist is facilitated through approximately 65,000 US community pharmacies. This creates billions of potential pharmacist-patient health care encounters each year. Unfortunately, America's pharmacists are somewhat underutilized by consumers in the drug therapy management process. The pharmacist-assisted self-care model of care fosters much needed pharmacist-patient interaction regarding drug therapy management.

**Economic Opportunities for Pharmacists**

If pharmacists are commodity vendors only and do not provide cognitive, meaningful information and clinical services to patients in the realm of nonprescription drug therapy, they will remain undifferentiated in the eyes of the consumer. Pharmacies will be viewed as no different from approximately 1 million other retail outlets that sell nonprescription drugs. A low pharmacist-service level will not attract self-medicating patients.

Today's pharmacist, however, is not undervaluing nonprescription drug therapy as a professional practice domain. Pharmacists see the opportunity in coordinating drug therapy management. Further, as profit margins decline on prescription drug sales, pharmacists are revitalizing nonprescription drug sales and services. Profit margins on nonprescription drugs are good. The average gross profit margin on nonprescription drugs is in the range of 32% to 36% vs. less than 25% on prescription drug sales. Further, most sales of nonprescription drugs involve first-party payment (''cash and carry''). Pharmacist-assisted self-care fosters business (economic) and professional (clinical) opportunities for pharmacists. However, the pharmacist should recommend only those products that have demonstrated safety and effectiveness.

## CALL TO ACTION

### Medication Misuse

The clinical and economic consequences of poorly managed and misused prescription and nonprescription drug therapy is staggering. Pharmacists need to differentiate themselves with consumers as a nonprescription drug therapy information specialist, and integrate that knowledge into the larger context of all patient drug therapy and nutritional supplement utilization.

### Nonprescription Pharmacotherapy in the Pharmacy Curriculum

A 2002 survey titled "National Curriculum Survey: Status of Instruction in Nonprescription Drug Therapy" was mailed to 82 colleges and schools of pharmacy and received a 46% response rate.[4] School of pharmacy curricula underemphasize pharmacist-assisted self-care and nonprescription drug therapy. Nonprescription drug therapy was inconsistently addressed by schools of pharmacy in terms of required vs. elective status, commitment of credit hours, assurance of core competencies, and integration of course content involving nonprescription drug therapy throughout the curriculum. This survey was repeated in 2005 and results compared to the 2002 baseline. Findings were presented at the 2006 AACP Annual Meeting.[5]

When evaluating the marketplace, patient behaviors and attitudes, the prevalence of nonprescription drug use (and misuse) and the opportunity that pharmacists have to guide nonprescription drug selection, use, and monitoring, many would argue that pharmacy curricula are not adequately preparing PharmD graduates to perform as providers of high-level, pharmacist-assisted self-care services.

Core practice-relevant, patient-centered competencies need to be assured in the first- through third-professional years and built upon in the fourth-professional year. The professional curriculum should apply an academic "sniff test" to the entire curriculum to assure that curricular content is relevant to the contemporary practice of pharmacy, addresses disease processes and systems that are highly prevalent in our society, and recognizes that the focus needs to be on imparting knowledge that has a high probability of being utilized (applied) by the pharmacist in serving the public health interest. This requires an intentional, introspective analysis of curricula and possibly the rebalancing of curricular content and credit hour distribution to allow integration of thought, critical thinking, problem-solving ability, and patient-centered care in all years of the pharmacy curriculum. When challenges of curricular relevance are raised, most objective thinkers in touch with the reality of the marketplace would likely recommend substantially greater curricular content in the area of nonprescription drug therapy. Although pharmacy education is not directed to help students successfully pass the North American Pharmacist Licensure Examination (NAPLEX), educators must recognize that the profession, through the National Association of Boards of Pharmacy, has placed nonprescription medicines on equal emphasis with prescription medicines for purposes of the NAPLEX examination.[6]

### Professional Initiatives

The profession of pharmacy is at a critical juncture. Profit margins on prescription drug sales continue to erode, with no end in sight. The Budget Reconciliation Act of 2006 authorizes the use of average manufacturer price (AMP) as the basis for prescription reimbursement for over 41 million Medicaid recipients, further eroding prescription-drug profitability. If this reimbursement methodology cascades into the commercial market, the economic consequences for pharmacy could be devastating. Gross margins on prescription drugs are now in a free-fall decline. Gross margins on nonprescription drugs significantly exceed gross margins on prescription drugs.

## SUMMARY

Unassisted nonprescription drug use and selection often lead to therapeutic misadventures and adverse clinical consequences for patients. Passive nonprescription commodity vendors cannot serve the public interest relative to nonprescription drug therapy. American pharmacy and individual pharmacists need to perceive their value-based, patient-focused pharmacist-assisted self-care role more clearly. However, perceiving this role correctly is not enough. Initiatives are needed on a large-scale basis by schools of pharmacy, state and national pharmacy organizations, pharmacy chains, pharmacy wholesalers, and individual pharmacists to evolve pharmacist-assisted self-care.

Initiatives must address intellectual preparedness and new professional practice and business models. Our nation cannot afford the luxury of having consumers and health professionals trivializing or undervaluing nonprescription drug therapy as a critical component of US health care.

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